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Dentistry - Materials for dental instruments - Part 2: Polymers (ISO 21850-2:2025)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 10/25

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EN ISO 21850-2

NORME EUROPÉENNE

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English Version

**Dentistry - Materials for dental instruments - Part 2:
Polymers (ISO 21850-2:2025)**Médecine bucco-dentaire - Matériaux pour instruments
dentaires - Partie 2: Polymères (ISO 21850-2:2025)Zahnheilkunde - Werkstoffe für Dentalinstrumente -
Teil 2: Polymere (ISO 21850-2:2025)

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EN ISO 21850-2:2025 (E)

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European foreword

This document (EN ISO 21850-2:2025) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 "Dentistry" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2025, and conflicting national standards shall be withdrawn at the latest by December 2025.

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Endorsement notice

The text of ISO 21850-2:2025 has been approved by CEN as EN ISO 21850-2:2025 without any modification.



International Standard

ISO 21850-2

Dentistry — Materials for dental instruments —

Part 2: Polymers

*Médecine bucco-dentaire — Matériaux pour instruments
dentaires —*

Partie 2: Polymères

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ISO 21850-2:2025(en)**Foreword**

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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ISO 21850-2:2025(en)**Introduction**

An increasing number of newly developed dental surgery techniques make use of procedures like dental implant placements. The market for dental instruments is also growing rapidly, alongside demand for new and better instruments.

This document is intended to support the harmonization of approval procedures and the reduction of costs caused by separate approval and test procedures in different countries with regard to the polymer materials used in dental instruments.

Dentistry — Materials for dental instruments —

Part 2: Polymers

1 Scope

This document specifies polymers commonly used in manufacturing dental instruments.

It is applicable to polymers used to manufacture either an entire instrument or part of an instrument.

It is applicable to single-use and reusable dental instruments, whether they are connected to a power-driven system or not.

This document does not apply to oral appliances and devices (e.g. splints, mouthpieces, crowns, bridges, implants), to instruments used long-term in the mouth of the patient or to devices and instruments not made of polymers.

This document contains a selection of polymers suitable for use in the manufacture of dental instruments.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 472, *Plastics — Vocabulary*

ISO 1043-1, *Plastics — Symbols and abbreviated terms — Part 1: Basic polymers and their special characteristics*

ISO 1942, *Dentistry — Vocabulary*

ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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